

## CLAIMS

1. Use of a preparation of an active enamel substance for the preparation of a pharmaceutical composition for the induction of apoptosis.
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2. Use of a preparation of an active enamel substance for the preparation of a pharmaceutical composition for the prevention or treatment of malignant or benign neoplasms.
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3. Use of a preparation of an active enamel substance for the preparation of a pharmaceutical composition for the prevention or treatment of cancer.
4. Use of a preparation of an active enamel substance for the preparation of a pharmaceutical composition for the (selective) induction of apoptosis in neoplastic cells.
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5. Use according to any of claims 1-4 wherein the preparation of active enamel substance is applied at or on tissue comprising a substantial proportion of epithelial cells.
6. Use according to claim 5 wherein said tissue comprises skin or mucosal tissue.
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7. Use according to claim 6 wherein the mucosal tissue comprises oral mucosa, gastrointestinal mucosa, mucosa of the respiratory tract (such as lung mucosa), cervical mucosa or abdominal mucosa.
8. Use according to claim 5 wherein the tissue is glandular tissue, e.g. mammary gland,
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pancreas, liver, thyroid gland, bladder, prostate, sweat gland, salivary gland or pituitary gland tissue.
9. Use according to any of claims 1-4 for the topical treatment of cancer or neoplasms.
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10. Use according to claim 8 wherein the cancer or neoplasm is selected from epithelially derived cancers or neoplasms.
11. Use according to claim 9 for application at or on a tumour site before, during or after a tumour operation to substantially reduce the risk of post-surgical metastasis or to substantially prevent recurrence of the tumour.
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12. Use according to any of the preceding claims, wherein the active enamel substance is enamel matrix, enamel matrix derivatives and/or enamel matrix proteins.

5 13. Use according to any of the preceding claims, wherein the active enamel substance is selected from the group consisting of enamelins, amelogenins, non-amelogenins, proline-rich non-amelogenins, amelins (ameloblastin, sheathlin), tuftelins, and derivatives thereof and mixtures thereof.

10 14. Use according to any of the preceding claims, wherein the active enamel substance has a molecular weight of at the most about 120 kDa such as, e.g., at the most 100 kDa, 90 kDa, 80 kDa, 70 kDa or 60 kDa as determined by SDS Page electrophoresis.

15 15. Use according to any of the preceding claims, wherein the preparation of an active enamel substance contains a mixture of active enamel substances with different molecular weights.

16. Use according to any of the preceding claims, wherein the preparation of an active enamel substance comprises at least two substances selected from the group consisting of amelogenins, proline-rich non-amelogenins, enamelins, tuftelin, tuft proteins, serum proteins, salivary proteins, amelin, ameloblastin, sheathlin, and derivatives thereof.

20 17. Use according to any of the preceding claims, wherein the active enamel substance has a molecular weight of up to about 40,000.

25 18. Use according to any of the preceding claims, wherein the active enamel substance has a molecular weight of between about 5,000 and about 25,000.

30 19. Use according to any of the preceding claims, wherein the major part of the active enamel substance has a molecular weight of about 20 kDa.

20. Use according to any of the preceding claims, wherein at least a part of the active enamel substance is in the form of aggregates or after application in vivo is capable of forming aggregates.

21. Use according to claim 20, wherein the aggregates have a particle size of from about 20 nm to about 1  $\mu\text{m}$ .

22. Use according to any of the preceding claims, wherein the protein content of the active enamel substance in the preparation is in a range of from about 0.05% w/w to 100% w/w such as, e.g., about 5-99% w/w, about 10-95% w/w, about 15-90% w/w, about 20-90% w/w, about 30-90% w/w, about 40-85% w/w, about 50-80% w/w, about 60-70% w/w, about 70-90% w/w, or about 80-90% w/w.

10 23. Use according to any of the preceding claims, wherein the pharmaceutical composition further comprises a pharmaceutically acceptable excipient.

15 24. Use according to claim 23, wherein the pharmaceutically acceptable excipient is propylene glycol alginate.

25. Use according to claim 23, wherein the pharmaceutically acceptable excipient is hyaluronic acid or salts or derivatives thereof.

20 26. Use according to any of claims 1-25 of EMDOGAIN® or any proteins or peptides contained therein for the induction of apoptosis.

27. A method for inducing of apoptosis in neoplastic cells, the method comprising applying an effective amount of an active enamel substance at or on neoplastic cells.

25 28. A method for preventing or treating malignant or benign neoplasms, the method comprising administering to a mammal in need thereof a prophylactically or therapeutically effective amount of an active enamel substance.

29. A method according to claim 28, wherein the active enamel substance is applied in an amount of total protein per  $\text{cm}^2$  area of affected tissue corresponding to from about 0.01 mg/ $\text{cm}^2$  to about 20 mg/ $\text{cm}^2$ , such as from about 0.1 mg/ $\text{cm}^2$  to about 15 mg/ $\text{cm}^2$ .

Add A<sup>1</sup>  
Add B<sup>2</sup>  
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